

CLAIMS

1. A process for the preparation of piroxicam: β -cyclodextrin inclusion compounds, comprising the following steps:
 - 5 a) dissolving piroxicam and β -cyclodextrin in the presence of ammonium hydroxide in a suitable tank containing water at a temperature of at least 60°C;
 - b) bringing the solution to a temperature of at least about -10°C;
 - c) further lowering the temperature of the frozen solution to at least
10 -20°C and preferably to between -30° and -40°C;
 - d) drying the frozen solution under vacuum.
2. A process as claimed in claim 1, characterized in that step b) is carried out by placing the solution on the temperature-controlled shelves of a freeze-dryer pre-cooled at at least -30°C.
- 15 3. A process according to claims 1-2, characterized in that step b) is carried at a rate equal to or higher than about 1°C/min.
4. A process as claimed in claim 1, characterized in that steps b) and c) are carried out by pouring the solution in a dewar filled with liquid nitrogen.
5. A process as claimed in claims 1-4, characterized in that step e) is
20 carried out by bringing the temperature of the shelves at 50-60°C.
6. A process as claimed in claim 1 characterized in that the β -cyclodextrin to piroxicam molar ratio is comprised between 4:1 and 1:1.
7. A process according to claim 6 characterized in that the β -cyclodextrin to piroxicam molar ratio is 2.5:1
- 25 8. A 1:2.5 piroxicam: β -cyclodextrin inclusion compound obtained by the process of claims 1 to 5, characterized by the Raman spectrum of Figure 1.
9. Pharmaceutical compositions containing as active ingredient the inclusion compound of claim 8 in admixture with suitable excipients.

10. Pharmaceutical compositions as claimed in claim 9 in the form of tablets containing between 50 and 200 mg of said complex per unit dose.